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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/598,443	06/22/2000	John Ernest Sims	03260.0044	5571

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	13

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary	Application No.	Applicant(s)	
	09/598,443	SIMS, JOHN ERNEST	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *27 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Receipt of Applicant's arguments, filed on 27 May 2003 in Paper No.12, is acknowledged. None of the claims has been cancelled or amended. Also no new claims have been added. Thus claims 34-60 are pending and under consideration.

2. The following previous objection is withdrawn in light of Applicants amendments filed in Paper No.12, 05/27/03:

(I) The rejection of claims 48-60 made under 35 U.S.C. 101 for reciting ".....a host cell...." is withdrawn. Applicants' argument that the recited host cell is "transfected" or "transduced" with a vector, which shows the intervention of a person to introduce a nucleic acid sequence into said host cell is persuasive to overcome this rejection.

(1I). The rejection of claim 59 for reciting "TIGIRR" is withdrawn.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 101/112

4a. Claims 34-60 stand rejected under 35 U.S.C. 101, for reasons of record, set forth in the office action mailed on 11/26/02 in Paper No:11, pages 3-7, and reiterated here, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Applicants submit the following arguments regarding this rejection.

Applicants' first argument is that instant specification provides a nucleic acid that is similar in sequence and general structure to IL-1 receptor (IL-1R) encoding nucleic acid. Applicants also argue that the claimed nucleic acid sequence has been mapped

to the chromosome 11p15.5 region, which is subject to loss of heterozygosity (LOH) in a number of diseases including Wilm's tumor, rhahbdomyosarcoma, breast cancer, non-small cell lung carcinoma (NSCLC), among other diseases. Thus, Applicants assert that the claimed nucleic acid can be used as a novel marker sequence to determine LOH for diagnostic and prognostic uses. Applicants further submit that the M.P.EP instructs Examiners that sufficient utility has been shown when the genomic locus is known. Applicants argue that the SIGIRR nucleic acid of the instant invention has substantial utility since it can used to detect LOH in individuals and these LOH events are associated with diseases. Applicants finally argue that they only need cite only one utility to satisfy the requirements under 35 U.S.C 101, and they have accomplished that.

Applicants' arguments have been fully considered but are not deemed persuasive.

Firstly, disclosing that the claimed nucleic acid encodes a protein that is similar in sequence and general structure to IL-1 receptor (IL-1R) does not impart a utility common to all the members of this family, because the specific activity and physiological role of the claimed nucleic acid and the encoded protein is not disclosed. Secondly, the fact that the claimed nucleic acid sequence has been mapped to chromosome 11p15.5 region, does not provide utility for the claimed nucleic acid. There is no doubt that that chromosome 11p15.5 is associated with loss of heterozygosity (LOH), in a number of diseases including Wilm's tumor, rhahbdomyosarcoma, breast cancer, non-small cell lung carcinoma (NSCLC), however, the role of the claimed nucleic acid in any of these diseases is not disclosed by Applicants. The claimed nucleic

acid can't be used to diagnose any disorder, because instant specification does not establish a link between the claimed nucleic acid and any disorder. High incidence of LOH might be observed in certain tumors, however, the specific role of the genes mapped on a locus of a chromosome associated with LOH must be delineated. For example, is there a reduction or over-production of said gene relative to control tissues? Instant specification does not demonstrate whether the claimed nucleic acid itself is involved in the recited diseases or whether it is the encoded protein. Is it the over-expression or under-expression of the claimed nucleic acid itself that is associated with these diseases? No meaningful information will be obtained from tracking the level of expression of the claimed nucleotide or mapping the locus on a chromosome in which the claimed DNA is located, because there is no physiological or biological significance attached to these nucleotides or the encoded proteins.

Therefore, since the function or biological significance of the claimed nucleic acid is yet undetermined, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility. Furthermore, in order for a nucleic acid to be useful, as asserted, for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed nucleic acid and a disease or disorder.

Contrary to Applicants' argument, knowing the genomic location of a gene is not sufficient to establish a specific utility, because 35 U.S.C. 101 demands that Applicants must also disclose what the invention is useful for.

Finally, Applicants are correct in that there is only one credible assertion of utility to satisfy the requirement under 35 U.S.C. 101, however, said assertion must also be specific and substantial. Instant specification fails to disclose the specific physiological role of the claimed nucleic acid, therefore, it fails to satisfy 35 U.S.C. 101.

4b. Claims 34-60 also stand rejected under 35 U.S.C. 112, first paragraph, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Applicants fail to disclose the physiological role of the claimed nucleic acid or the encoded protein, therefore, one of ordinary skill in the art would not know how to use the claimed invention.

Conclusion

5. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary d. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Fozia Hamud
Patent Examiner
Art Unit 1647
August 11, 2003